

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

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ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

18 September 2008 (18.09.2008)

Applicant's or agent's file reference

DEXCOM.027QP

IMPORTANT NOTICE

International application No.

PCT/US2006/034284

International filing date (day/month/year)

01 September 2006 (01.09.2006)

Priority date (day/month/year)

09 March 2006 (09.03.2006)

Applicant

DEXCOM, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference DEXCOM.027QP	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2006/034284	International filing date (day/month/year) 01 September 2006 (01.09.2006)	Priority date (day/month/year) 09 March 2006 (09.03.2006)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant DEXCOM, INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

Date of issuance of this report
09 September 2008 (09.09.2008)

Authorized officer

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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Daniel Hart
Knobbe Martens Olson & Bear LLP
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

17 AUG 2007

Applicant's or agent's file reference
DEXCOM.027QP

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US 06/34284

International filing date (day/month/year)
01 September 2006 (01.09.2006)

Priority date (day/month/year)
09 March 2006 (09.03.2006)

International Patent Classification (IPC) or both national classification and IPC
IPC(B) - A61B 5/00 (2007.01)
USPC - 600/345

Applicant
Dexcom, Inc.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion
20 April 2007 (20.04.2007)

Authorized officer:

Lee W. Young

PCT Headset: 571-272-4300
PCT DES: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 06/34284

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ on paper
☐ in electronic form
 - c. time of filing/furnishing
☐ contained in the international application as filed
☐ filed together with the international application in electronic form
☐ furnished subsequently to this Authority for the purposes of search
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>2,6-9,11,13,17-20,22,25,26,28,30,31,34-37,39,40,43-46,48 & 51</u>	YES
	Claims	<u>1,3-5,10,12,14-16,21,23,24,27,29,32,33,38,41,42,47,49 & 50</u>	NO
Inventive step (IS)	Claims	<u>None</u>	YES
	Claims	<u>1-51</u>	NO
Industrial applicability (IA)	Claims	<u>1-51</u>	YES
	Claims	<u>None</u>	NO

2. Citations and explanations:

Claims 1, 3-5, 10, 12, 14-16, 21, 23, 24, 27, 29, 32, 33, 38, 41, 42, 47, 49 and 50 lack novelty under PCT Article 33(2) as being anticipated by US 2005/0043598 A1 to Goode et al (hereinafter "Goode").

Regarding claims 1 and 12, Goode discloses method and system for analyzing data from an analyte sensor, comprising:

- a) receiving sensor data from the analyte sensor (para [0274]);
- b) the sensor data comprising at least two sensor data points (para [0304]); and
- c) calculating a rate of change of the sensor data from the sensor data points (para [0321]).

Regarding claims 3 and 14, Goode discloses the step of smoothing the sensor data points, wherein the step of smoothing is conducted prior to the step of calculating the rate of change (para [0274]).

Regarding claims 4 and 15, Goode discloses the step of smoothing being conducted using at least one of a moving average window, a regression, a finite impulse response filter, and an infinite impulse response filter (para [0328]).

Regarding claims 5 and 16, Goode discloses the step of calibrating the sensor data, wherein the step of calculating the rate of change is performed on non-calibrated sensor data (para [0311]).

Regarding claims 10 and 21, Goode discloses the step of determining if the rate of change is above a predetermined threshold or below a predetermined threshold (para [0324]).

Regarding claim 23, Goode discloses a system for analyzing data from an analyte sensor, the system comprising:

- a) a data receiving module configured to receive sensor data from the analyte sensor (para [0274]);
- b) the sensor data comprising at least two sensor data points (para [0304]); and
- c) a processor module configured to calculate a rate of change of the sensor data from the sensor data points substantially without artifacts caused by noise in the sensor data (para [0327]).

Regarding claim 24, Goode discloses the processor module being configured to smooth the sensor data points to accomplish calculation of a rate of change of the sensor data from the sensor data points substantially without artifacts caused by noise in the sensor data (para [0328]).

Regarding claim 27, Goode discloses that the processor module is configured to detect noise in the sensor data (para [0358]).

Regarding claims 29 and 38, Goode discloses a method and system for analyzing data from an analyte sensor, the method comprising:

- a) receiving data from the analyte sensor, the data comprising at least one sensor data point (para [0274]);
- b) receiving reference data from a reference analyte monitor, the reference data comprising at least one reference data point (para [0305]); and
- c) determining an acceptability of the sensor data or the reference data by subjecting the reference data and substantially time-corresponding sensor data to a boundary test utilizing boundaries (para [0306]).

Regarding claims 32 and 41, Goode discloses the step of determining acceptability of the reference data, wherein a positive determination of acceptability is determined when the reference data and substantially time-corresponding sensor data fall within the boundaries of the boundary test (para [0306]).

Regarding claims 33 and 42, Goode discloses using the reference data for calibration of the analyte sensor in response to a positive determination of acceptability (para [0307] and [0311]).

— See continuation sheet —

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.2 - Citations and explanations:

Regarding claim 47, Goode discloses a system for analyzing data from an analyte sensor, the system comprising:

- a) a sensor data receiving module configured to receive sensor data from the analyte sensor, the sensor data comprising at least one sensor data point (para [0274]);
- b) a reference data receiving module configured to receive reference data from a reference analyte monitor, the reference data comprising at least one reference data point (para [0305]); and
- c) a processor module configured to perform outlier detection on the reference data or the sensor data, wherein the processor module is further configured to calibrate the analyte sensor (para [0339] and [0311]).

Regarding claim 49, Goode discloses comparing reference data and time-corresponding sensor data to a boundary test (para [0359]).

Regarding claim 50, Goode discloses that the processor module is configured to detect noise in the sensor signal (para [0358]).

Claims 2, 6-9, 11, 13, 17-20, 22, 25, 26, 28, 30, 31, 34-37, 39, 40, 43-46, 48 and 51 lack an inventive step under PCT Article 33(3) as being obvious over Goode.

Regarding claims 2 and 13, Goode teaches the claimed invention but does not specifically teach the step of calculating a rate of change comprising calculating a rate of change of the sensor data from at least three sensor data points. Goode teaches the use of a data stream comprising one or more data points (para [0304]) and it would have been obvious to use at least three data points as this would improve the accuracy of any calculation.

Regarding claims 6 and 17, Goode teaches the claimed invention but does not specifically teach determining when at least three sensor data points increase continuously or decrease continuously, wherein the step of calculating the rate of change is performed only when at least three sensor data points increase continuously or decrease continuously. Goode does teach a process of continuous signal estimation in order to reduce signal artifacts in determining consistent detection has been ascertained. It would have been obvious to one skilled in the art that Goode could be modified in order to achieve this through determining the rate of change over three sensor data points as this would be a very efficient process.

Regarding claims 7 and 18, Goode teaches the claimed invention but does not specifically teach the step of calculating a rate of change value for at least two pairs of sensor data points. Goode teaches the use of pairs of data points (para [0307]) and it would have been obvious to one skilled in the art that Goode could be modified to calculate the rate of change over two or more pairs of data to achieve a more accurate result.

Regarding claims 8 and 19, Goode as modified above teaches the claimed invention and further teaches the step of smoothing the rate of change value (para [0274]).

Regarding claims 9 and 20, Goode as modified above teaches the claimed invention and further teaches the step of smoothing the rate of change value comprising utilizing at least one of a moving average window, a regression, a finite impulse response filter, and an infinite impulse response filter (para [0328]).

Regarding claims 11 and 22, Goode does not specifically teach the predetermined threshold being a positive 2 mg/dL/min or a negative 2 mg/dL/min. However, Goode does teach a threshold of about 4 to 5 mg/dL/min. It would have been obvious to one skilled in the art would contemplate a threshold of 2 mg/dL/min to provide more delicate monitoring.

Regarding claim 25, Goode teaches the claimed invention but does not specifically teach the processor module being configured to calculate a rate of change value for at least two pairs of sensor data points. However, Goode teaches the use of pairs of data points (para [0307]) and it would have been obvious to one skilled in the art that Goode could be modified to calculate the rate of change over two or more pairs of data to achieve a more accurate result.

Regarding claim 26, Goode as modified above teaches the claimed invention and further teaches that the processor module is further configured to smooth the rate of change value (para [0274]).

Regarding claim 28, Goode as modified above teaches the claimed invention but does not specifically teach that the processor module is configured to calculate the rate of change dependent at least in part upon whether the noise is detected. Goode does teach the detection of noise (para [0358]) and it would have been obvious to one skilled in the art that it would be beneficial to only calculate the rate of change when the signal is free of noise and that Goode could easily be modified to achieve this.

Regarding claims 30 and 39, Goode teaches the claimed invention but does not specifically teach that the boundaries are derived from prior information. The boundaries (para [0306]) appear to be based on experience and it would have been obvious to one skilled in the art that prior information would be the most effective way of setting the boundaries.

Regarding claims 31 and 40, Goode as modified above teaches the invention but does not specifically teach that the prior information comprises information obtained from at least one of in vivo testing or at least one analyte sensor and in vivo use of at least one analyte sensor. However, a common way for calibrating sensors generally is to perform control tests prior to deployment and it would have been obvious to one skilled in the art that Goode could be modified to make use of this information in setting boundary conditions.

— see continuation sheet —

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.2 - Citations and explanations:

Regarding claims 34 and 43, Goode teaches the claimed invention but does not specifically teach requesting additional reference data in response to a negative determination of acceptability. However, it would have been obvious to one skilled in the art that Goode could be modified to request further data should it fall outside the said boundaries as otherwise there would be no data to analyse.

Regarding claims 35 and 44, Goode as modified above teaches the claimed invention and further teaches determining acceptability of the additional reference data, wherein a positive determination of acceptability is determined when the additional reference data and substantially time-corresponding sensor data fall within the boundaries of the boundary test.

Regarding claims 36 and 45, Goode as modified above teaches the claimed invention and further teaches using the additional reference data for calibration of the analyte sensor in response to a positive determination of acceptability of the additional reference data (para [0307] and [0311]).

Regarding claims 37 and 46, Goode as modified above teaches the claimed invention and further teaches using the reference data for calibration of the analyte sensor if the additional reference data substantially corresponds to the reference data (para [0307], matched data pairs).

Regarding claim 48 and 51, Goode teaches the claimed invention but does not specifically teach that the processor module is configured to calibrate the analyte sensor after the system has successfully passed outlier detection or when noise is substantially not detected in the sensor signal. However, it would be obvious to one skilled in the art that it would be beneficial to only calibrate the sensor after erroneous data has been removed and that Goode could be simply modified to perform this.

Claims 1-51 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.